

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Celecoxib versus placebo as an adjunct in the treatment of Adolescents with bipolar mood disorder: a double blind randomized, placebo controlled study.

Protocol summary

Summary

The objective of this study is to compare the effects of celecoxib and placebo in the treatment of adolescent bipolar mood disorder in a double-blind clinical trial. Blinding is done for two groups of subjects and raters of the outcomes of the study. Forty children and adolescent patients aged 12 to 18 years with diagnosis of acute phase of bipolar disorder and meeting inclusion criteria will be chosen from Roozbeh Psychiatric Hospital. After obtaining consent from patients they will enter into the double-blind treatment with lithium and risperidone and placebo or lithium and risperidone and celecoxib and the severity of symptoms before treatment and at weeks two, four and eight after treatments will be assessed. Effect of two treatment methods on patients' overall performance will be evaluated before and at eighth week after treatment. All patients will be treated with lithium and risperidone. Patients will be evaluated in terms of side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080423478N1**

Registration date: **2016-05-09, 1395/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-09, 1395/02/20

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences, DR Masud Younesian

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Celecoxib versus placebo as an adjunct in the treatment of Adolescents with bipolar mood disorder: a double blind randomized, placebo controlled study.

Public title

Celecoxib versus placebo as an adjunct in the treatment of Adolescents with bipolar mood disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Bipolar disorder (first episode); acute illness episode; manic phase; and Young Mania Rating Scale score 20 or more; age 12 to 18 years Exclusion criteria: Liver, kidney, heart and thyroid disorders at

present; history of renal dysfunction or heart or a history of stomach ulcers; hypersensitivity to sulfonamides; co-morbidity risk of autism spectrum disorders; the risk of mental retardation; substance abuse over the past year; Mood Disorder caused by physical illness such as seizures; head trauma and other diseases

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Research Deputy of Tehran University of Medical Sciences, Keshavarz Avenue

City

Tehran

Postal code

Approval date

2015-08-04, 1394/05/13

Ethics committee reference number

IR.TUMS.REC.1394.517

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31.1, F31

ICD-10 code description

Bipolar affective disorder, current episode manic without

psychotic symptoms

Primary outcomes

1

Description

Bipolar disorder

Timepoint

Second week, Forth week, Week eight

Method of measurement

YMRS scale

Secondary outcomes

1

Description

Patient function

Timepoint

Before treatment and at week eight

Method of measurement

CGAS Scale

Intervention groups

1

Description

Intervention group: All patients treated with lithium , and risperidone and celecoxib. The dose of celecoxib is 100 mg twice a day.

Category

Treatment - Drugs

2

Description

Control group: All patients treated with lithium , risperidone and placebo. All patients received a starting dose of risperidone combined with lithium 1 mg in all patients, and within 10 days of the final dose (3 mg) will be.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Child and Adolescent Psychiatric, Rouzbeh Hospital.

Full name of responsible person

Seyed Yaser Musavi

Street address

Rouzbeh Hospital ,South Kargar Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences, DR Masud Younesian

Full name of responsible person

Mrs. Karimi

Street address

Research Deputy of Tehran University of Medical Sciences, Keshavarz Avenue, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences, DR Masud Younesian

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Seyd Yaser Musavi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty